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# Superdisintegrants in Orally Administered Products of Pharmaceuticals: A Review

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## ABSTRACT

Superdisintegrants are developed to improve the palatability in orally administered products and to advancing the development of various formulations with increase performance and acceptability. Superdisintegrants are used to revise the potency of solid dosage form .This is accomplish by decreasing the disintegration time which in turn improvement the drug dissolution rate. Diverse categories of Superdisintegrants such as synthetic, semi synthetic, natural and cross-processed blend etc. The present study comprises the various kinds of Superdisintegrants which are being used in formulations to provide the safer effective drug delivery with patient's compliance.

***KEYWORDS:*** *Orally administered products; Superdisintegrants; potency; palatability*

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## INTRODUCTION

On analyzing the behavior of disintegration time in the oral cavity as well as wetting time by surface free energy we came to know, that for a faster wetting a molecule should have high polar component of surface free energy and the agents which meet these special requirements are called as Superdisintegrants [1].

Superdisintegrants are those substances, which facilitate the faster disintegration with smaller quantity in contrast to disintegrants. The disintegration of dosage forms are depends upon various physical factors of disintegrants/Superdisintegrants which are as follow:

1. Percentage of disintegrants present in the formulation
2. Proportion of disintegrants used
3. Compatibility with other excipients.
4. Presence of surfactant.
5. Hardness of the tablets.
6. Nature of Drug substances
7. Mixing and types of addition.[2,3]

Superdisintegrants are added version of super-absorbing materials with tailor-made swelling properties. These materials are not planned to absorb significant amounts of water or aqueous fluids, but planned to swell very fast. Superdisintegrants are used as a structural weakener for the disintegrable solid dosage forms. They are physically dispersed within the matrix of the dosage form and will expand when the dosage form is exposed to the wet environment. [4]. These newer substances are more effective at lower concentrations with greater disintegrating efficiency and mechanical strength.[5] Superdisintegrants are generally used at a low level in the solid dosage form, typically 1 - 10 % by weight relative to the total weight of the dosage unit. [6] Their particles are generally small and porous, which allow for rapid tablet disintegration in the mouth without an objectionable mouth-feel from either large particles or gelling. The particles are also compressible which improves tablet hardness and its friability.[4] Effective Superdisintegrants provide improved compressibility, compatibility and have no negative impact on the

mechanical strength of formulations containing high-dose drugs.[7]

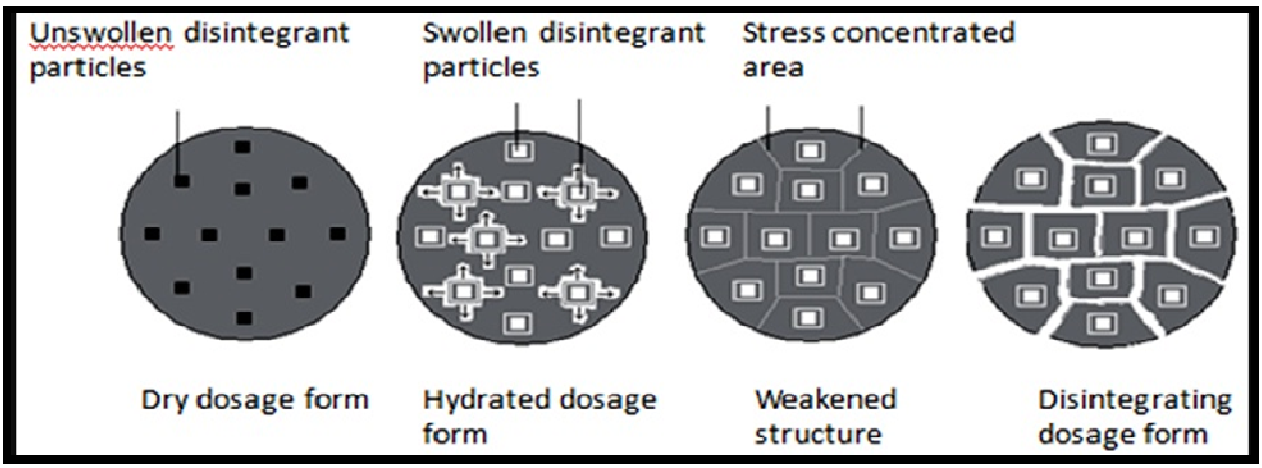


**Figure. 1: Disintegration Mechanism of Superdisintegrants materials**

**1.1. Selection of Superdisintegrants** [4, 8]: Since Superdisintegrants is used as an excipient in the tablet formulation; it has to meet certain criteria other than its swelling properties. The requirement placed on the tablet disintegrant should be clearly defined. The ideal disintegrant should have -

1. Poor solubility.
2. Poor gel formation.
3. Good hydration capacity.
4. Good moulding and flow properties.
5. No tendency to form complexes with the drugs.
6. Good mouth feel.
7. It should also be compatible with the other excipients and have desirable tableting properties.

**1.2. Advantages of Superdisintegrants** [9-11]

1. Remarkable tendency on wetting causing rapid disintegration.
2. No lump formation on disintegration.
3. Compatible with commonly used therapeutic agents and excipients.
4. Does not stick to the punches and dyes.
5. Effective in lower concentrations.
6. Less effect on compressibility and flow ability.
7. More effective intragranularly.
8. Some are anionic and may cause some slight in vitro binding with cationic drugs.
9. Biodegradable.

**1.3. Disadvantages of Superdisintegrants** [12]

1. Expensive.
2. Time consuming and fragile.
3. More sensitive and hygroscopic in nature

**1.4. Ideal Properties of Superdisintegrants** [13-16]

1. It should produce rapid disintegration.
2. It should produce good moulding and flow property.
3. It should have good particle size, good hydration capacity and compressibility index.
4. It should have poor water solubility.
5. It should produce compactable less friable tablets.
6. Effective at very low concentration and should have greater disintegrating efficiency.
7. Nontoxic and should have good mouth feel.
8. It should have no tendency to form complexes with the drugs.
9. It should be compatible with the other excipients and should have desirable tableting properties.

**1.5. Types of Superdisintegrants**

**Natural Superdisintegrants**

**Xanthan Gum**

Xanthan gum which is derived from Xanthomonas campestris is official in USP with high hydrophilicity and low gelling tendency. It has low water solubility and extensive swelling properties for faster disintegration [17].

**Gellan Gum**

It is a linear anionic polysaccharide biodegradable polymer obtained from Pseudomonas elodea consisting of a linear tetra saccharide repeat structure. The disintegration of tablet might be due to the instantaneous swelling characteristics of Gellan gum when it comes into contact with water and owing to its high hydrophilic nature [18]. The complete disintegration of tablet is observed within 4 minutes with Gellan gum at a concentration of 4 percent w/w [19].

**Mango Peel Pectin**

Dried mango peel powder is used for extracting pectin. Mango peel pectin due to its good swelling index and good solubility in biological fluids can be used to prepare fast dispersible tablets [12]. Mango peel which constitutes 20– 25% of the mango processing waste was found to be a good source for the extraction of pectin of good quality, suitable for the preparation of film and acceptable jelly[20].

**2. Synthetic Superdisintegrants**

**Synthetic Superdisintegrants**

Modified Starch (Sodium starch glycolate, Primojel) Sodium starch glycolate is the sodium salt of a carboxymethyl ether of starch. These are modified starches made by crosslinking of potato starch as it gives the product with the best disintegrating properties. The degree of cross-linking and substitution are important factors in determining the effectiveness of these materials as superdisintegrants. The effect of the crosslinking is to reduce both the water soluble fraction of the polymer and the viscosity of dispersion in water. The natural pre dried starches swell in water to an extent of 10-20 percent and the modified starches increase in volume by 200-300 percent in water. The mechanism by which this action takes place involves rapid absorption of water leading to an enormous increase in volume of granules that result in rapid and uniform disintegration [14, 21]. The tablets formulated by using these superdisintegrants may disintegrate in less than two minutes.

**Cross-linked Polyvinyl Pyrrolidone (Crospovidone)**

Crospovidone quickly wicks saliva into the tablet to generate the volume expansion and hydrostatic pressure necessary to provide rapid disintegration in the mouth. When examined under a scanning electron microscope, a crospovidone particle appears to be granular and highly porous. This unique, porous nature facilitates wicking of liquid into the dosage systems and causes rapid disintegration. In contrast to other superdisintegrants such as sodium starch glycolate and croscarmellose sodium, crospovidone exhibit virtually no tendency towards gel formation, even at a high ratio[22] . Crosspovidones are highly compressible materials as a result of their unique particle morphology. Crospovidone is used as superdisintegrant at low concentration levels (2-5%) in direct compression, wet and dry granulation processes [23]. The polymer has a small particle size distribution that imparts a smooth mouth feel to dissolve quickly. Varieties of grades are available commercially as per their particle size in order to achieve a uniform dispersion for direct compression with the formulation.

**Alginates**

These are hydrophilic colloidal ingredients that are extracted naturally from certain types of kelp or chemically improved from natural sources like alginic acid or alginic acid salts. Alginic acid is a polymer derived from seaweeds comprising D-mannuronic and L-glucoronic units. Its affinity for water absorption and high sorption capacity makes it an excellent disintegrant. Alginic acid is used as disintegrant at 1-5 % concentration while sodium alginate at 2.5-10 % concentration. It can be successfully used with ascorbic acid and multivitamin formulations [24, 25].

**1.6. Method of Incorporation of Superdisintegrants**

The incorporation of superdisintegrants in the dosage forms are mainly of three types:

1 Intragranular or during granulation: In this process the superdisintegrants are blend with other powders and granulation is carried out. Thus the superdisintegrants are incorporated within the granules.

2 Extragranular or prior to compression: In this process, the superdisintegrants are mixed with prepared granules before compres

3 Incorporation of Superdisintegrants at intra and extra granulation steps*:* In this process part of superdisintegrants are added to intragranular and a part to extragranules. This method usually produces better results and more complete disintegration than type 1 and type 2 [26]

**1.7. Mechanism of Action of Superdisintegrants**

There are five major mechanisms for tablet disintegration as follows:-

1. Swelling
2. Porosity and Capillary Action (Wicking)
3. Deformation
4. Enzymatic reaction
5. Due to disintegrating particle/particle repulsive forces

1.7.1 Swelling: Swelling is believed to be a mechanism in which certain disintegrating agents (such as starch) impart the disintegrating effect. By swelling in contact with water, the adhesiveness of other ingredients in a tablet is overcome causing the tablet to fall apart [27]. Such as Sodium starch glycolate, Platago Ovata shows swelling properties. [28-29, 13]

1.7.2 Porosity and Capillary Action (Wicking): Effective disintegrants that do not swell are believed to impart their disintegrating action through porosity and capillary action. Tablet porosity provides pathways for the penetration of fluid into tablets. The disintegrant particles (with low cohesiveness & compressibility) themselves act to enhance porosity and provide these pathways into the tablet. Liquid is drawn up or "wicked" into these pathways through capillary action and rupture the interparticulate bonds causing the tablet to break apart.E.g.Crospovidone, Croscarmellose Sodium [14]

1.7.3 Deformation: Starch grains are generally thought to be "elastic" in nature meaning that grains that are deformed under pressure will return to their original shape when that pressure is removed. But, with the compression forces involved in tableting, these grains are believed to be deformed more permanently and are said to be "energy rich" with this energy being released upon exposure to water. In other words, the ability for starch to swell is higher in "energy rich" starch grains than it is for starch grains that have not been deformed under pressure [28-29]

1.7.4 By Enzymatic Reaction**:** Enzymes present in the body also act as disintegrants. These enzymes dearth the binding action of binder and helps in disintegration. Due to swelling, pressure is exerted in the outer direction that causes the tablet to burst or the accelerated absorption of water leads to an enormous increase in the volume of granules to promote disintegration [29]

1.7.5 Due to disintegrating particle/particle repulsive forces*:* Another mechanism of disintegration attempts to explain the swelling of tablet made with "nonswellable" disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that nonswelling particle also cause disintegration of tablets. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it. Researchers found that repulsion is secondary to wicking. It is believed that no single mechanism is responsible for the action of most disintegrants. But rather, it is more likely the result of inter-relationships between these major mechanisms [29]

**Conclusion:**

Superdisintegrants are developed to improve the palatability in orally administered products and to advancing the development of various formulations with increase performance and acceptability. Superdisintegrants are used to revise the potency of solid dosage form. While, there are various Superdisintegrants, the search for innovative disintegrating agents is in progress and investigators are investigating through improvement in natural products like, mango peel pectin, Xanthan Gum and Gellan gum**.** The investigation gives some Superdisintegrants exam like Cross-linked Polyvinyl Pyrrolidone and Alginates and their mechanism**.** Therefore, in coming period, there is going to be continued attention for the development of orally administered products by using appropriate Superdisintegrants.

**Conflict of interest**

The authors declare that they have no conflict of interest

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